

***New England Compounding Pharmacy, Inc. –***  
**Application for a New Store-date received 2/18/1998.**



COPY

The Commonwealth of Massachusetts  
**Division of Registration**  
Leverett Saltonstall Building,  
Government Center  
100 Cambridge Street, Boston MA 02202

**BOARD OF REGISTRATION IN PHARMACY**

**APPLICATION FOR A NEW STORE**

2848

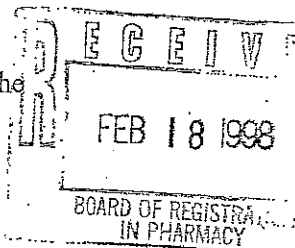
7/16/58

State Board approved with  
licensees provided signs  
and labels do not use  
word Pharmacy, copy

I hereby apply for a permit to conduct and keep open a store for the transaction of the retail drug business in accordance with the provisions of Chapter 112, General Laws.

\$175.00 fee for applying for licensure. The check or money order should be made out to the Commonwealth of Massachusetts. This fee is nonrefundable.

All information must be typewritten.



1. Legal Name of Business: New England Compounding Pharmacy, Inc.
2. Full Business Address (Street Address, City, State and Zip): 697 Waverly Street,  
Framingham, MA 01701
3. Area Code and Telephone Number: (401) 334-1937 (temporary)
4. All trade or business names ("D.B.A." names) used by same Corporation or by Licensee N/A
5. Type of ownership or operation (i.e., sole proprietorship, partnership, corporation): Corporation

If corporation, please submit articles of corporation. Attached hereto as Exhibit "A"

6. Name(s) and Social Security Number(s) of the owner(s) and/or operator(s) of the licensee. Please indicate type of ownership - Partnerships: the name of each partner and name address of partnership; Corporations: the name and title of each corporate officer and director, the corporate names, name and address of parent company, if any, and the State of incorporation; Sole Proprietorships: the name of the sole proprietor and the address of the business entity.

Officers: Carla Conigliaro, President/Treasurer, Director: Gregory Conigliaro,  
Clerk, Director: Barry J. Cadden, Vice President, Director: Lisa M. Conigliar  
Assitant Treasurer, Director.  
Parent Company: N/A  
State of incorporation: Massachusetts

See additional information required for corporations attached hereto as Exhibit "B"

2652

7. Name of registered pharmacist charged with the management of the pharmacy: Barry J. Cadden

8. Registration number of above manager: #21239 ✓ O-R

9. Name(s) and registration number(s) of staff pharmacist(s) employed at pharmacy  
Lisa M. Conigliaro Cadden, #21096 ✓

10. Have any of the applicant(s) and/or managers-in-charge had: 1) any convictions related to the distribution of drugs (including samples); 2) any felony convictions; 3) any suspension(s) or revocation(s) or other sanction(s) by federal, state or local governmental agency of any license or registration currently or previously held by the applicant or licensee for the manufacture, distribution, or dispensing of any drugs, including controlled substances? Have any applications for licensure been denied by any federal or state agency including any state boards of pharmacy? List and explain. Attach additional sheets if necessary. No

11. The applicant/licensee must notify the Board in writing of any changes in ownership or management within thirty (30) days of such change(s).

Affidavit (must be completed and notarized)

Pursuant to M.G.L. c. 62C, s. 49A, I certify under the penalties of perjury that I, to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes required under law.

The applicant certifies that each person employed in any prescription drug distribution activity has the education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law.

I hereby state that I am the person authorized to sign this application for all licensure; that all statements are true and correct in all respects and are made under the penalties of perjury.

Barry J. Cadden

*Signature of pharmacist who is to manager the pharmacy or pharmacy department*

Barry J. Cadden

2/9/98

*Date*

*Social Security Number of managing pharmacist*

Sworn and subscribed before me this 9th day of February 1998

My commission expires

June 16 2000

Notary Public

#175

3556

2/20/98

COPY

D

The Commonwealth of Massachusetts

William Francis Galvin

Secretary of the Commonwealth

One Ashburton Place, Boston, Massachusetts 02108-1512

ARTICLES OF ORGANIZATION

(General Laws, Chapter 156B)

Examiner

Name

Approved

ARTICLE I

The exact name of the corporation is:

New England Compounding Pharmacy, Inc.

ARTICLE II

The purpose of the corporation is to engage in the following business activities:

(a) To provide, own, manage, and operate a pharmacy or pharmacies and to provide general and specific pharmacy services.

(b) To do any other acts and things, and to exercise any and all other powers which a corporation organized under the provisions of Massachusetts General Laws Chapter 156B and acts additional and amendatory thereto could do and exercise which now or hereafter may be authorized.

C ☐  
P ☐  
M ☐  
RA. ☐

Note: If the space provided under any article or item on this form is insufficient, additions shall be set forth on one side only of separate 8 1/2 x 11 sheets of paper with a left margin of at least 1 inch. Additions to more than one article may be made on a single sheet so long as each article requiring each addition is clearly indicated.

P.C.

### ARTICLE III

State the total number of shares and par value, if any, of each class of stock which the corporation is authorized to issue.

WITHOUT PAR VALUE		WITH PAR VALUE		
TYPE	NUMBER OF SHARES	TYPE	NUMBER OF SHARES	PAR VALUE
Common:	200,000	Common:	N/A	
Preferred:	N/A	Preferred:	N/A	

### ARTICLE IV

If more than one class of stock is authorized, state a distinguishing designation for each class. Prior to the issuance of any shares of a class, if shares of another class are outstanding, the corporation must provide a description of the preferences, voting powers, qualifications, and special or relative rights or privileges of that class and of each other class of which shares are outstanding and of each series then established within any class.

N/A

### ARTICLE V

The restrictions, if any, imposed by the Articles of Organization upon the transfer of shares of stock of any class are:

N/A

### ARTICLE VI

\*\*Other lawful provisions, if any, for the conduct and regulation of the business and affairs of the corporation, for its voluntary dissolution, or for limiting, defining, or regulating the powers of the corporation, or of its directors or stockholders, or of any class of stockholders:

See continuation sheet Article VI attached hereto.

\*\*If there are no provisions state "None".

Note: The preceding six (6) articles are considered to be permanent and may ONLY be changed by filing appropriate Articles of Amendment.

#### ARTICLE VII

The effective date of organization of the corporation shall be the date approved and filed by the Secretary of the Commonwealth. If a *later* effective date is desired, specify such date which shall not be more than *thirty days* after the date of filing.

#### ARTICLE VIII

The information contained in Article VIII is not a permanent part of the Articles of Organization.

a. The street address (*post office boxes are not acceptable*) of the principal office of the corporation in *Massachusetts* is:

697 Waverly Street, Framingham, MA 01701

b. The name, residential address and post office address of each director and officer of the corporation is as follows:

	NAME	RESIDENTIAL ADDRESS	POST OFFICE ADDRESS
President:	Carla Conigliaro	[REDACTED]	Same
Treasurer:	Carla Conigliaro	[REDACTED]	Same
Clerk:	Gregory Conigliaro	[REDACTED]	Same
Directors:	Carla Conigliaro	[REDACTED]	Same
	Gregory Conigliaro	[REDACTED]	Same
	Barry J. Cadden	[REDACTED]	Same
	Lisa M. Conigliaro	[REDACTED]	Same
	Cadden	[REDACTED]	Same

c. The fiscal year (i.e., tax year) of the corporation shall end on the last day of the month of:  
December 31

d. The name and business address of the resident agent, if any, of the corporation is:

#### ARTICLE IX

By-laws of the corporation have been duly adopted and the president, treasurer, clerk and directors whose names are set forth above, have been duly elected.

IN WITNESS WHEREOF AND UNDER THE PAINS AND PENALTIES OF PERJURY, I/we, whose signature(s) appear below as incorporator(s) and whose name(s) and business or residential address(es) are *clearly typed or printed* beneath each signature do hereby associate with the intention of forming this corporation under the provisions of General Laws, Chapter 156B and do hereby sign these Articles of Organization as incorporator(s) this 31 day of January, 19 98.

*Carla Conigliaro*

*Note: If an existing corporation is acting as incorporator, type in the exact name of the corporation, the state or other jurisdiction where it was incorporated, the name of the person signing on behalf of said corporation and the title he/she holds or other authority by which such action is taken.*

NEW ENGLAND COMPOUNDING PHARMACY, INC.

CONTINUATION SHEET ARTICLE VI

ARTICLE 6A INDEMNIFICATION OF OFFICERS AND DIRECTORS

The Corporation shall, to the extent legally permissible, indemnify any person serving or who has served as a Director or Officer of the Corporation, or at its request as a Director, Trustee, Officer, Employee or other Agent of any organization in which the Corporation owns shares or of which it is a creditor, against all liabilities and expenses, including amounts paid in satisfaction of judgments, in compromise or as fines and penalties, and counsel fees, reasonably incurred by him/her in connection with the defense or disposition of any action, suit or other proceedings, whether civil or criminal, in which he/she may be involved or with which he/she may be threatened, while serving or thereafter, by reason of his/her being or having been such a Director, Officer, Trustee, Employee, or Agent, except with respect to any matter as to which he/she shall have been adjudicated in any proceeding not to have acted in good faith in the reasonable belief that his/her action was in the best interest of the Corporation; provided, however, that as to any matter disposed of by a compromise payment by such Director, Officer, Trustee, Employee or Agent, pursuant to a consent decree or otherwise, no indemnification either for said payment or for any other expenses shall be provided unless:

- (a) such compromise shall be approved as in the best interests of the Corporation, after Notice that it involves such indemnification:
  - (i) by a disinterested majority of the Directors then in office; or
  - (ii) by the holders of a majority of the outstanding stock at the time entitled to vote for Directors, voting as a single class, exclusive of any stock owned by any interested Director or Officer; or
- (b) in the absence of action by disinterested Directors or stockholders, there has been obtained at the request of a majority of the Directors then in office an opinion in



NEW ENGLAND COMPOUNDING PHARMACY, INC.

writing of independent legal counsel to the effect that such Director or Officer appears to have acted in good faith in the reasonable belief that his/her action was in the best interests of the Corporation.

Expenses including counsel fees, reasonably incurred by any such Director, Officer, Trustee, Employee or Agent in connection with the defense or disposition of any such action, suit or other proceeding may be paid from time to time by the Corporation in advance of the final disposition thereof upon receipt of any undertakings by such individual to repay the amounts so paid to the Corporation if it is not ultimately determined that indemnification for such expenses is not authorized under this section. The right of indemnification hereby provided shall not be exclusive of or affect any other rights to which any such Director, Officer, Trustee, Employee or Agent may be entitled. Nothing contained in this Article shall affect any rights to indemnification to which Corporation personnel other than such Directors, Officers, Trustees, Employees or Agents may be entitled by contract or otherwise under law. As used in this Article the terms "Director", "Officer", "Trustee", "Employee", and "Agent" include their respective heirs, executors, administrators, and an "interested" Director, Officer, Trustee, Employee or Agent is one against whom in such capacity the proceedings in question or other proceedings on the same or similar grounds is then pending.

ARTICLE 6B TRANSACTIONS WITH INTERESTED PERSONS

1. Unless entered into in bad faith, no contract or transaction by this Corporation shall be void, voidable or in any way affected by the fact that it is with an Interested Person.
2. For the purpose of this Article "Interested Person" means person or organization in any way interested in this Corporation as an officer, director, stockholder, employee, or otherwise, or any entity in which any such person or organization or this Corporation is in any way interested.
3. Unless such contract or transaction was entered into in bad faith, no Interested person, because of such interest, shall be liable to this Corporation or to any other person or organization

NEW ENGLAND COMPOUNDING PHARMACY, INC.

for loss or expense incurred by reason of such contract or transaction which shall be accountable for any gain or profit realized from such contract or transaction.

4. The provisions of this Article shall be operative notwithstanding the fact that the presence of an Interested Person was necessary to constitute a quorum at a meeting of directors or stockholders of this Corporation at which such contract or transaction was authorized or that the vote of an Interested Person was necessary for the authorization of such contract or transaction

ARTICLE 6C STOCKHOLDERS' MEETINGS

Meetings of stockholders of this Corporation may be held anywhere in the United States.

ARTICLE 6D AMENDMENT OF BY-LAWS

The By-Laws may provide that the Board of Directors as well as the stockholders may make, amend, or repeal the By-laws of this Corporation, except with respect to any provision thereof which by these Articles or by the By-Laws requires action by the stockholders.

ARTICLE 6E SALE OF ASSETS; DISSOLUTION

The terms and conditions upon which a sale or exchange of all the property and assets, including the good will of the Corporation, or any part thereof, is voted may include the payment therefore in whole or in part in shares, notes, bonds, or other certificates of interest or indebtedness of any voluntary association, trust, joint-stock company or Corporation. Such vote or a subsequent or a subsequent vote may in the event of or in contemplation of proceedings for the dissolution of the Corporation also provide, subject to the rights of creditors and proffered stockholders, for the distribution pro rata among the stockholders of the Corporation, of the proceeds of any such sale or exchange, whether such proceeds be in cash or in securities as aforesaid (at values to be determined by the Directors).

NEW ENGLAND COMPOUNDING PHARMACY, INC.

ARTICLE 6F PARTNERSHIP

This Corporation may become a partner in any general or limited partnership or in any joint venture or in any other business enterprise organized for the purpose of accomplishing any of the purposes contained in this Corporation's Articles of Organization.

ARTICLE 6G RIGHT OF OFFICERS, DIRECTORS AND STOCKHOLDERS TO CONTRACT WITH A CORPORATION

The Corporation may contract and otherwise transact business with any of its Directors, Officers and Stockholders and with corporations, joint stock companies, trusts, firms and associations in which any of them are or may be or become substantially interested as directors, officers, shareholders, members, trustees, beneficiaries or otherwise as freely as though such adverse interest did not impart upon such contract or transaction. No such contract or transaction shall be avoided and no such Director, Officer or stockholder shall be liable to account to the Corporation for any profit realized by him through any such contract or transaction by reason of such adverse interest, not by reason of any fiduciary relationship to such Director, Officer or stockholder to the Corporation arising out of such office or stock ownership; provided the nature of the adverse interest of such officer or director or stockholder shall have been made known to nor disclosed by the Board of Directors by said person prior to such contract or transaction. Ownership of beneficial interest in an insubstantial amount of the stock or securities of another corporation, joint stock company, trust, firm or association shall not be deemed to constitute an interest adverse to this Corporation and need not be disclosed. The authorizing or ratifying vote of a majority of the shares of the common stock of the Corporation outstanding and entitled to vote shall validate any such contract or transaction as against all stockholders of the Corporation, whether of record or not at the time of such vote, and as against all creditors and other claimants; provided that such vote shall have been passed at a meeting duly called and held for that specific purpose. No contract or transaction shall be avoided by reason of any provisions of this paragraph which would be valid but for these provisions.

THE COMMONWEALTH OF MASSACHUSETTS

ARTICLES OF ORGANIZATION

(General Laws, Chapter 156B)

I hereby certify that, upon examination of these Articles of Organization, duly submitted to me, it appears that the provisions of the General Laws relative to the organization of corporations have been complied with, and I hereby approve said articles; and the filing fee in the amount of \$ \_\_\_\_\_ having been paid, said articles are deemed to have been filed with me this \_\_\_\_\_ day of \_\_\_\_\_ 19 \_\_\_\_\_.

Effective date: \_\_\_\_\_

WILLIAM FRANCIS GALVIN

*Secretary of the Commonwealth*

**FILING FEE:** One tenth of one percent of the total authorized capital stock, but not less than \$200.00. For the purpose of filing, shares of stock with a par value less than \$1.00, or no par stock, shall be deemed to have a par value of \$1.00 per share.

TO BE FILLED IN BY CORPORATION

Photocopy of document to be sent to:

Tamkin & Hochberg, LLP

313 Washington Street, Suite 202

Newton, MA 02158

Telephone: 617-964-2501

**NEW ENGLAND COMPOUNDING PHARMACY  
APPLICATION FOR REGISTRATION OF NEW PHARMACY**

OFFICERS

President/Treasurer: Carla Conigliaro

Vice President: Barry J. Cadden

Clerk: Gregory Conigliaro

Asst. Treasurer: Lisa M. Conigliaro Cadden

DIRECTORS

Carla Conigliaro

Barry J. Cadden

Gregory Conigliaro

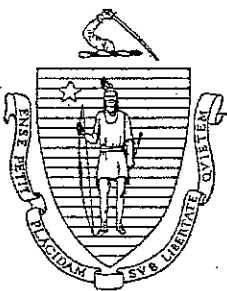
Lisa M. Conigliaro Cadden

STOCKHOLDERS

NAME	ADDRESS	SHARES	TYPE
Carla Conigliaro	[REDACTED]	650 Shares	No Par
Barry J. Cadden	[REDACTED]	125 Shares	No Par
Gregory Conigliaro	[REDACTED]	100 Shares	No Par
Lisa M. Conigliaro Cadden	[REDACTED]	125 Shares	No Par

D/B/A NAME

None



The Commonwealth of Massachusetts  
Division of Registration  
Leverett Saltonstall Building, Government Center  
100 Cambridge Street, Boston MA 02202

Cash: \_\_\_\_\_ Check: \$75-

No. \_\_\_\_\_ Date: \_\_\_\_\_ M.O. \_\_\_\_\_

Business: \_\_\_\_\_ Location: \_\_\_\_\_

Please do not write above this line  
Fee \$75.00 Non-Refundable

I here apply for Registration under Mass. Controlled Substances Act-M.G.L. 94C Section 7.

Applicant Name: (if an individual) New England Compounding Pharmacy, Inc.

Business Address: 697 Waverly <sup>(Last)</sup> Street <sup>(First)</sup> <sup>(Middle)</sup>  
(No. and Street)  
Framingham MA 01701  
(City or Town) (State) (Zip Code)

Registration Classification:

(a) X Retail Drug Store (b) \_\_\_\_\_ Wholesale/Mfg/Dist.  
(c) \_\_\_\_\_ Hospital/Clinic/Inst. (d) \_\_\_\_\_ Nuclear

FEIN # \_\_\_\_\_

Drug Schedule

Schedule II Schedule III (X) Schedule IV (X) Schedule V (X) Schedule VI  
( ) Non-Narcotic ( ) Non-Narcotic  
(X) Narcotic (X) Narcotic

Current drugstore permit No.: \_\_\_\_\_ Current Wholesale Druggist License No.: \_\_\_\_\_

Pharmacist's Registration No.: 21239

Signature of Applicant: Barry J. Cadden 2/9/98  
Barry J. Cadden  
(Owner of facility must sign application)

Please submit check or money order payable to Commonwealth of Mass.-Board of Registration in Pharmacy

WARNING:

In accordance with Chapter 94 M.G.L. Sec 13, the Board of Registration in Pharmacy in the case of a retail drug business or wholesale druggist, may suspend or revoke a registration to manufacture, distribute, dispense or possess a controlled substance after a hearing pursuant to the provisions of Chapter 34A upon finding that the registrant has furnished false or fraudulent information in any application filed under the provisions of Chapter 94C.



*The Commonwealth of Massachusetts*

*Division of Registration*

*Leverett Saltonstall Building, Government Center  
100 Cambridge Street, Boston 02202*

PHARMACY HOURS\*

NAME OF PHARMACY: New England Compounding Pharmacy, Inc.

STREET ADDRESS: 697 Waverly Street

CITY / TOWN: Framingham ZIP CODE: 01701

PHONE NUMBER: (401) 334-1937 (temporary)

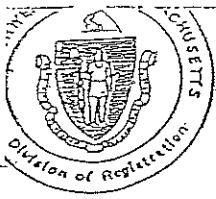
	OPEN	CLOSE	HOURS
MONDAY	<u>9:00</u>	<u>5:00</u>	<u>8.0</u>
TUESDAY	<u>9:00</u>	<u>5:00</u>	<u>8.0</u>
WEDNESDAY	<u>9:00</u>	<u>5:00</u>	<u>8.0</u>
THURSDAY	<u>9:00</u>	<u>5:00</u>	<u>8.0</u>
FRIDAY	<u>9:00</u>	<u>5:00</u>	<u>8.0</u>
SATURDAY	<u>          </u>	<u>          </u>	<u>          </u>
SUNDAY	<u>          </u>	<u>          </u>	<u>          </u>

TOTAL HOURS PER WEEK: 40.00

\*Initial hours; subject to modification.

Date: 2/9/78

Signature of Manager: Barry J. Cadden  
Barry J. Cadden



# Commonwealth of Massachusetts

## BOARD OF REGISTRATION IN PHARMACY

Leverett Saltonstall Building  
100 Cambridge St., Room 1514  
Boston, Ma, 02202.

### APPLICATION FOR CERTIFICATE OF FITNESS

MANAGER MUST COMPLETE APPLICATION

FEE \$60.00 Non-Refundable

I, Barry J. Cadden Telephone: (401) 334-1937  
(Your name)  
Address: 697 Waverly Street  
(Street and Number)  
Framingham MA 01701  
(City or Town) (State) (Zip Code)

a registered pharmacist, certificate number 21239 being now actively engaged in  
conducting a retail drug business ~~as sole owner or for the firm~~ corporation of

New England Compounding Pharmacy, Inc.

(Give name of ~~firm or~~ corporation)

(Draw a line through words which do not apply)

do hereby apply for Certificate of Fitness, claiming to be a proper person to be  
instructed with the authority:

- (1) To use alcohol for the manufacture of U.S.P. and N.F. preparations and  
all medicinal preparations unfit for beverage purposes.
- (2) To sell in accordance with the laws of the Commonwealth, alcohol and alcoholic  
liquors and that the public good will be promoted by the granting thereof.

I have \$5,000.00 dollars invested in said retail drug business and will  
(give amount in figures)  
comply with the laws of this Commonwealth and the regulations of the Board relating  
to the use and sale of the alcohol and alcoholic liquors.

I certify that I have not been convicted of violation of said laws within one  
year prior to the date thereof.

I agree to notify the Board at once if I cease to conduct the retail drug  
business at the above location and will return the certificate issued thereon.

Date: 2/9/98 (Signed) Barry J. Cadden  
(Signature of Manager)  
Barry J. Cadden

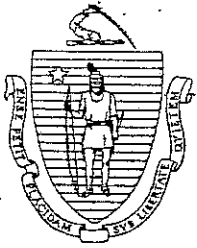
Fee of \$60.00 must be sent with this application. Please make checks payable  
to Comm of Mass/Board of Registration in Pharmacy.

#### FOR OFFICE USE ONLY

Cash \_\_\_\_\_ Check \_\_\_\_\_

N.O. \_\_\_\_\_ No. \_\_\_\_\_ Date \_\_\_\_\_





# *The Commonwealth of Massachusetts*

## *Division of Registration*

*Leverett Saltonstall Building, Government Center*

*100 Cambridge Street, Boston 02202*

### **PETITION FOR A WAIVER OF THE PROVISIONS OF 247 CMR FOR LICENSURE OF A PHARMACY/PHARMACY DEPARTMENT**

Application to be completed by the registered pharmacist who is or shall be responsible for the management and operation of the pharmacy/pharmacy department.

Pursuant to 247 CMR 14.01, I hereby apply for a special or limited-use pharmacy or pharmacy department permit because the type of pharmacy practice is of a special, limited or unusual nature as compared to a regular pharmacy service.

Name of pharmacy/pharmacy department: New England Compounding Pharmacy, Inc.

Location: 697 Waverly Street  
Framingham, MA 01701

Phone number: (401) 334-1937 (temporary)

Please use separate sheets to complete the following and attach sheets to application:

1. List the regulatory requirement(s) for which a waiver is requested and provide an explanation as to why each regulation should not apply to the pharmacy/ pharmacy department.
2. Explain the compelling public interest that would be served by the granting of a waiver.
3. Explain why adherence to the regulation(s) would be impractical and unduly burdensome.
4. Include a comprehensive statement of the policies and procedures of the proposed operation, including safeguards to protect the public health, welfare and safety.

Before acting upon any petition the Board may require the applicant to personally appear before the Board to answer questions that would enable the Board to determine that the issuance of a permit would be in the best interest of the public health, welfare and safety and adherence to 247 CMR would be unreasonable.

Upon the granting of a waiver and issuance of a special or limited-use permit, the Board will issue a written finding that recites the specific Board regulation(s) which are being waived, the reasons the Board is waiving the regulation (s) at issue, and lists and contingent restrictions under which the pharmacy or pharmacy department may operate.

I declare that the statements and answered herein contained are true and are made under the pains and penalties of perjury.

Barry J. Cadden  
Signature of pharmacist manager of record

Barry J. Cadden

2/9/98  
Date

**NEW ENGLAND COMPOUNDING PHARMACY, INC.**  
**PETITION FOR WAIVER OF BOARD REGULATIONS**

1. List the regulatory requirement(s) for which a waiver is requested and provide an explanation as to why each regulation should not apply to the pharmacy/pharmacy department.

A waiver is requested for 247 CMR 6.02(4): "The pharmacy...shall maintain on the premises at all times a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed medications in accordance with the usual needs of the community."

The applicant requests a waiver of this requirement because New England Compounding Pharmacy ("NECP") because NECP will offer a unique blend of products and services, distinguishing it from the full service pharmacy. NECP will specialize in pharmaceutical compounding and nutritional health products, and thus should not be required to provide the full range of commercially available pharmaceutical products.

The current art and science of compounding involves the preparation of suspensions, topicals, and suppositories; the conversion of one dosage form to another; the preparation of select dosage forms from bulk chemicals; the preparation of intravenous mixtures, parenteral nutrition solutions, and pediatric dosage forms from adult dosage forms; the preparation of radioactive isotopes; and the preparation of cassettes, syringes, and other drugs for administration in the home setting. These types of functions do not require the availability of the full range of pharmaceutical products, but rather only limited and specialized products.

2. Explain the compelling public interest that would be served by the granting of a waiver.

There is a compelling public interest which will be served by granting the waiver. The responsibility to extemporaneously compound safe, effective prescription products for patients who require special care is fundamental to the pharmacy profession.

A large number of patients experience problems with standard prescription drugs because of allergies to dyes and preservatives, the inability to swallow, and the need for unique quantities or medication or for a more palatable dosage form. As a result, many physicians are demanding more customized products in an effort to control outcomes and increase the effectiveness of prescribed treatments. Compounding gives the physician control over the form and strength of the medicines when commercial preparations are not acceptable.

By satisfying the needs of physicians through the preparation of specialized medications, NECP will provide optimal pharmaceutical care to the community. NECP will be one of but a few pharmacies designed especially to meet such needs. As the number of compounding pharmacies now located in the Metrowest region is limited, NECP will be vital to the community.

Allowing NECP to specialize in compounding prescriptions serves the public interest in a

variety of other ways as well. The pharmacists can devote the majority of their time to research and preparation of prescribed medications and to maintaining proficiency through current awareness and training. The distraction of the rote, mechanical, high volume dispensing of commercial products is removed.

Instead, pharmacists can pay strict attention to the National Association of Boards of Pharmacy's "Good Compounding Practices Applicable to State Licensed Pharmacies." Specifically, the pharmacists can thoroughly understand and comply with state compounding regulations; the facility can be staffed with appropriate personnel wearing appropriate attire; the facility can be state of the art with appropriate cleanliness, lighting, ventilation, and storage capabilities; the equipment can be of appropriate design and size, suitable located and properly cleaned and maintained, eliminating the possibility of cross contamination; components, drug product containers, and closures can be handled and stored properly; drug compounding controls can be extensive and meticulous; and labeling, records, and reports can be handled most efficiently. A compounding laboratory can be stocked with a wide range of products to respond immediately to the demands of physicians and patients. In sum, this type of specialization will lead to an improved practitioner knowledge base, increased efficiencies, and cost containment through economies of scale.

**3. Explain why adherence to the regulation(s) would be impractical and unduly burdensome.**

Adherence to 247 CMR 6.02(4) would be impractical and unduly burdensome to NECP. Having to dispense a wide variety of commercially available prescription medications in addition to compounding would place great time constraints on the pharmacists. There would be little time for one-on-one contact with patients and other health care professionals, which would lead to the improper education of patients on the use of the compounded prescriptions.

Without a waiver, NECP would be forced to compete with the larger full-service chain pharmacies for business. Additionally, without a waiver, the cost of maintaining the inventory required for a full-service pharmacy would require a larger space than that currently available to NECP.

**4. Include a comprehensive statement of the policies and procedures of the proposed operation, including safeguards to protect the public health, welfare, and safety.**

NECP will operate in conformance with all rules and regulations of the Commonwealth of Massachusetts, its Board of Registration in Pharmacy, and the National Association of Boards of Pharmacy ("NABP") Model State Pharmacy Act. All NECP pharmacists will be specially trained and educated in all aspects of pharmaceutical compounding to ensure that only quality compounds are provided for its patients.

NECP will use the Professional Compounding Centers of America, Inc. ("PCCA") as its source of chemicals and compounding supplies. The PCCA is registered and inspected by the Food

and Drug Administration and the Drug Enforcement Agency. The PCCA follows stringent quality control procedures which are unique among drug repackagers. Also, chemicals received by the PCCA are guaranteed until their identity is verified in a quality control lab. By using only the highest quality raw materials, NECP will produce safe, effective, and high quality compounded medications for its patients.

NECP will utilize a professional compounding computer program designed specifically for a compounding pharmacy lab. This program is based upon the NABP's recommendations for labeling and reports for compounded products, including stability and sterility information. This specialized computer system will aid NECP pharmacists in the production of quality pharmaceutical compounds.

NECP will only compound for patients with valid prescription orders approved by a practitioner who is licensed to prescribe in the Commonwealth of Massachusetts. All compounds will be produced in a state-of-the-art compounding laboratory following strict protocol to ensure that only quality compounds are produced. Such protocol will be based upon the attached NABP guidelines for preparing quality compounds (Exhibit "A"), clean bench operations (Exhibit "B"), and creating a controlled environment (Exhibit "C").

# PREPARING A QUALITY COMPOUND

## Quality Assessment:

- A. Does the chemical fit the description? Check the following:
1. Particle shape and size
  2. Color
  3. Quantity
  4. Smell, taste, and touch as needed using caution

EXHIBIT  
11

## Quality Control:

- A. Only prepare one medication at a time. Never work on two separate medications at the same time.
- B. Weighing chemicals
1. Check weights before and after weighing.
  2. Make sure the right amount of chemical is being weighed. **LOOK AT IT!** Also, check your weights.
  3. Protocols for preparation:
    - a. Retrieve a formula sheet/card or prepare a new one.
    - b. Print the labels and check the chemical name, lot number and expiration date.
    - c. With the formula sheet in your hand, check each chemical as you retrieve it.
    - d. Place all chemicals to be weighed on one section of the counter; place all chemicals that have already been weighed on another section of the counter; i.e., to the left or right of the balance. **HAVE A SYSTEM!**
    - e. Check the chemical name as you weigh it.
    - f. Check each chemical as you record it in your compounding log. **NEVER USE BRAND NAMES!**
    - g. When you are finished preparing your medication, check each chemical as you return it to the stock area.

## Quality Assurance:

- A. Examine the medication
1. Look, taste, smell and touch it as needed using caution.
  2. Is the amount prepared correct?
  3. Compare with a standard formula.
  4. Consistency and color.

5. Write down the characteristics of the final medication of the original batch and then note variations on each additional batch.
6. Check the label.
7. Are you sure you are correct?
8. Deliver the medication promptly, professionally, and profitably!
9. Patient Consultation about the completed compound. i.e. patient acceptance.

B. Quality control

1. Capsules

- a. Capsule weight variation

$$\frac{\text{Theoretical Weight} - \text{Actual Weight}}{\text{Theoretical Weight}} \times 100 = \% \text{ Error}$$

- b. Even color distribution/uniformity

- c. Similar particle size of powders

d. \_\_\_\_\_

e. \_\_\_\_\_

2. Eye drops

- a. pH

- b. Clarity

- c. Color

- d. Aseptic technique used

e. \_\_\_\_\_

f. \_\_\_\_\_

3. Injections

- a. pH

- b. Clarity

- c. Color

- d. Aseptic technique used

e. \_\_\_\_\_

f. \_\_\_\_\_

4. Solutions/Suspensions

- a. pH

- b. Color

- c. Clarity

- d. Viscosity

- e. Taste

- f. Odor

- g. Uniformity
- h. Aseptic technique used
- i. \_\_\_\_\_
- j. \_\_\_\_\_

5. Suppositories

- a. Color
- b. Uniformity
- c. Weight variation
- d. Melting point
- e. \_\_\_\_\_
- f. \_\_\_\_\_

6. Troches

- a. Color
- b. Uniformity
- c. Weight variation
- d. Melting point
- e. Taste
- f. \_\_\_\_\_
- g. \_\_\_\_\_

7. Creams/Ointments/Lotions/Gels

- a. Color
- b. Uniformity
- c. Odor
- d. Smoothness
- e. Grittiness
- f. pH
- g. Viscosity
- h. Aseptic technique used
- i. \_\_\_\_\_
- j. \_\_\_\_\_

*Continuous Quality Improvement:*

- A. Upgrade facility
- B. Upgrade procedures

**Expiration/Use By Data:**

A. Stability Criteria

1. Physical or chemical properties of active ingredients
2. Use of preservatives and/or stabilizing agents
3. Dosage forms
4. Storage conditions
5. Scientific laboratory or reference data

B. Merck Index

C. Martindale's Pharmacopeia

D. Remington's

E. Hospitals (M.D. Anderson's)

F. PCCA

G. Trissel's Stability of Compounded Formulations

H. Handbook on Injectable Drugs

I. Physicians Desk Reference

J. Drug Facts and Comparisons

K. Hansten/Horn Drug Interactions

L. Trissel's Tables

M. \_\_\_\_\_

N. \_\_\_\_\_

O. \_\_\_\_\_

P. \_\_\_\_\_

Q. \_\_\_\_\_



# CLEAN BENCH OPERATIONS

## (Laminar Flow Hood)

### Purpose:

To define policy and outline procedures to be followed for all operations conducted in the clean bench environment.

### Policy:

The Pharmacist shall designate strict procedures and maintain quality control over the aseptic operations conducted in the clean bench areas.

These standards will apply to:

1. Cleanliness of the area
2. Maintenance of the clean bench and laminar flow hood
3. Aseptic technique of personnel operating in the area
4. Working standards for personnel

### Procedure:

#### Maintaining a Clean Area

1. The floor of the room is to be cleaned no less than once daily.
2. Activities that do not require aseptic technique are to be conducted in another area of the department.
3. All equipment and materials are to be stored in their proper places when not in use on the bench. No items are to be placed on top of the clean bench laminar flow hood.

#### Maintaining the Clean Bench Laminar Flow Hood

1. Allow the blower to run continuously.
2. Establish and follow a schedule for changing the prefilters in each hood at least once each month.
3. Make periodic measurements of the air velocity from the HEPA filter in the clean bench. Velocity should be 90 - 100 ft./min., with 70 ft./min. as an action point.
4. No objects, sharply pointed or otherwise, should be permitted to contact the HEPA filter.
5. Photometer leak detections should be conducted on an annual basis or upon any relocation of the clean bench laminar flow hood.

EXHIBIT  
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### Performance Standards for Working in the Clean Bench Area

1. First thing in the morning, wipe the clean bench work surface with alcohol 70%.
2. In addition, wash work-surface areas with distilled water followed with alcohol 70% before and after all aseptic manipulations.
3. Activities in the clean bench laminar flow hood should be maintained at a normal pace. Rushing will cause turbulence.
4. Exclude from the work-surface area sulfur-containing materials, such as horse hair, masking tape, pencils, paper, and rags.
5. A five-minute scrub of hands, arms, and elbows should be made with an antiseptic cleanser just prior to entering the hood.
6. Personnel should refrain from wearing excessive face powder, rouge, fingernail polish, or any other cosmetics.
7. Whenever possible, keep the product being manipulated directly exposed to the HEPA filter face. In other words, keep the product "upstream" of the hands, equipment, and materials (toward the HEPA filter).
8. All non-sterile items should be rinsed (washed down) with alcohol 70% prior to entry into the laminar flow environment.
9. All items should be arranged in the laminar flow environment so that a minimum of air turbulence results and the flow of clean air is not blocked. This can be achieved best by arranging them in the following manner:
  - a. The object should be placed into the clean bench work area so that laminar flow is free to flow around it.
  - b. The object should be located no less than three times its width from the open end of the unit (preferably, three times its width plus 6", if space allows).
  - c. Objects should be placed so that a maximum amount of space exists laterally between them.
10. All aseptic work must be performed at least 6" from the open end of the laminar flow unit.
11. In cases where the nature of the operation makes it necessary to have items or portions of the items "upstream" from the product, take extreme care to maintain cleanliness of the "upstream" surface.

### Quality Control:

Inspections of all clean bench centers shall be conducted during the last week of each month. Also, at this time the supervisor of the area and the quality control pharmacist will coordinate a report regarding the personnel and aseptic technique utilized in the area.

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## A CONTROLLED ENVIRONMENT

The following is a list of suggested materials and specifications for building a "Controlled Environment" in which to place a laminar flow hood for aseptic compounding.

	Minimum	Maximum
<b>Flooring</b>	<ul style="list-style-type: none"> <li>• Vinyl Floor (Sheet Style)</li> <li>• Epoxy Painted Cement</li> </ul>	<ul style="list-style-type: none"> <li>• Terrazzo Tile</li> <li>• Dex Otex Epoxy</li> <li>• PVC (Tarkett)</li> </ul>
<b>Walls</b>	<ul style="list-style-type: none"> <li>• Washable High Gloss Enamel</li> <li>• Washable High Gloss Epoxy</li> </ul>	<ul style="list-style-type: none"> <li>• Stainless Steel Sheets</li> <li>• PVC Sheeting</li> </ul>
<b>Ceiling</b>	<ul style="list-style-type: none"> <li>• Suspended Grid Vinyl Inserts</li> <li>• Gypsum Board Painted with High Gloss Enamel</li> </ul>	<ul style="list-style-type: none"> <li>• Same as walls</li> </ul>
<b>Doors</b>	<ul style="list-style-type: none"> <li>• Washable High Gloss Enamel</li> <li>• Formica Covered Door</li> </ul>	<ul style="list-style-type: none"> <li>• Stainless Steel</li> <li>• PVC Coated Wood</li> </ul>

EXHIBIT

### NOTES AND COMMENTS:

You must have a minimum of 20 air changes per hour for Class 100,000, and 50 air changes per hour for Class 10,000.

Laminar flow hoods are Class 100; that is, less than 100 particles at .05 microns per cubic foot.

Class 100 hoods should be surrounded by Class 10,000 clean rooms.

To create a higher air pressure in your room, it is necessary to build all four walls past the suspended ceiling to the roof. Your room should be supplied with a separate H.V.A.C. system in which the return air supply from the room is less than the fresh air coming from the system into the room. This creates a positive pressure in your room.

If you are remodeling your current building, you may get greater pressure inside your room by simply closing off the return air in your compounding room.

Positive pressure can sometimes be achieved by lowering the pressure in an adjacent room.

Avoid floor tiles and 90 degree angles where flooring meets walls. Both tiles and 90 degree angles are havens for particulate matter.

A large picture window in the room is nice because it gives the technician a feeling of not being isolated. Visitors are also able to see your high tech area without going into the controlled environment.

Avoid window ledges: flush mounted fixtures have less surface on which particulate matter can collect.

Ensure that there is enough room to accommodate your laminar flow hood, two people, a six foot storage cabinet area, and six feet of counter space for completed work.

Doors do not necessarily have to be sealed, providing there is positive pressure in the room. The door should either be a sliding door or it should open to the outside so the draft takes clean air to unclean air, and not vice versa.

Provide a place for an anteroom where you keep cardboard boxes and supplies.

**Who is one of the largest producers of particulate matter?**

**WE ARE!** A person at rest generates at least 100,000 particles per minute. Nodding yes to a co-worker on the other side of a window generates 500,000 particles. Walking from one end of the cleanroom to the other generates 5 million particles. A simple sneeze generates 1.4 million, and a cough, 2.8 million; not to mention the result of hair spray, dead skin tissue, make-up, dandruff, etc.

So, the worst thing we can put in a cleanroom is a person. Just picture Pig Pen from the Peanuts® cartoon.

**What can we do to cut down on Pig Pen?**

**Write strict guidelines and follow them!**

1. Have a tacky mat at the entrance to the anteroom. Always step on the tacky mat before entering.
2. Wear a head bonnet, foot covers, a lab coat or coveralls, and gloves.
3. Do not wear make-up, hair spray, cologne or perfume, finger nail polish, or jewelry, just to mention a few.

**RULE OF THUMB:** If it is not necessary, do not wear it.

4. Always wash thoroughly with a good hospital-type soap. Follow up with a good moisturizer without fragrance.
5. Upon entering the cleanroom via the anteroom, stand very still for a moment to let the particulate matter that entered with you settle.
6. Move slow and steady while in the cleanroom. Train yourself not to touch your face.
7. No eating, drinking, or gum chewing in the cleanroom.

## CLEANING SOLUTIONS:

A variety of cleaning solutions are available commercially through local wholesalers and hospital suppliers. Household cleaning solutions are not suggested.

A 70% isopropyl alcohol can be used and is very effective in killing bacteria; however, a higher concentration of alcohol in some cases can act as a preservative due to its hygroscopic qualities.

Sodium Hypochlorite (bleach) and 2 oz. to 1 gallon of water is another effective disinfectant. Caution must be used to avoid mixing with other detergents.

## CLEANING PROCEDURES:

Cleanrooms should be free of bacteria. The only way to achieve this is to clean and maintain by continuously cleaning the room. Here are a few suggestions to achieve a bacteria-free cleanroom.

1. Cleaning supplies used in the cleanroom should only be used in the cleanroom. You do not want cross-contamination from another room to the cleanroom.
2. Mops and wipes should be lint free. Sponges are not recommended due to the particulate matter they retain, and they are difficult to clean. The same problem applies to the standard string mops.

**TAMKIN & HOCHBERG, LLP**

**Attorneys at Law**

313 Washington Street, Suite 202

Newton, Massachusetts 02158

Tel (617) 964-2501

Fax (617) 964-7755

Jonathan D. Tamkin, P.C.

Andrew S. Hochberg, P.C.\*

Karen E. Dumser

\*Also admitted in Connecticut

February 25, 1998

RECEIVED

FEB 27 1998

BOARD OF REGISTRATION  
IN PHARMACY

Of Counsel

Alvin C. Tamkin

Eugene M. Magier, P.C.

Charles R. Young, Acting Executive Director  
Board of Registration in Pharmacy  
100 Cambridge Street  
Boston, MA 02202

RE: New England Compounding Pharmacy  
Registration Application

Dear Mr. Young:

Enclosed as supplementary to the application of New England Compounding Pharmacy, Inc., please find a certified copy of the corporation's Articles of Organization.

Also, please be advised that New England Compounding Pharmacy, Inc.'s federal identification number is 04-3407495. Please note the same on our client's Controlled Substances Application.

Should you have any questions regarding the above, please contact me.

Sincerely,  
TAMKIN & HOCHBERG, LLP

BY:

Jonathan D. Tamkin

IDT/

Enclosure

cc: Carla Conigliaro  
Barry J. Cadden

**TAMKIN & HOCHBERG, LLP**

**Attorneys at Law**

313 Washington Street, Suite 202  
Newton, Massachusetts 02158  
Tel (617) 964-2501  
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Jonathan D. Tamkin, P.C.  
Andrew S. Hochberg, P.C.\*

Karen E. Dumser

\*Also admitted in Connecticut

Mr. Charles Young  
Acting Executive Director  
Division of Registration  
Board of Registration in Pharmacy  
100 Cambridge Street, 15th Floor  
Boston, MA 02202

Of Counsel

Alvin C. Tamkin  
Eugene M. Magier, P.C.

RECEIVED  
June 15 1998

JUN - 3

RE: New England Compounding Pharmacy, Inc.

Dear Mr. Young:

As you know, this office is counsel to New England Compounding Pharmacy, Inc. ("NECP"). This will confirm our recent telephone conversation, in conjunction with the Board of Registration in Pharmacy's approval on April 14, 1998, of our client's application for a new pharmacy to be located at 697 Waverly Street, Framingham, MA. You advised me that the Board had voted to grant our client's application for a waiver of 247 CMR 6.02(4) permitting our client to limit its stock of medicinal chemicals and preparations as its requires to operate its specialized compounding pharmacy. As a condition of the grant of such waiver, you advised me that the Board required our client to modify its name, for signage purposes, by the eliminating the word "Pharmacy" so as to avoid any confusion for walk in consumers.

Accordingly, per our discussion, I enclose for your records a copy of our client's Business Certificate filed with the Town of Framingham identifying its trade name as New England Compounding Center. Such name will be used on all signage related to the pharmacy. Our client is presently obtaining its final municipal construction inspections and will be contacting the Board in the next week or so to arrange for the Board's final inspection of the pharmacy.

Thank you for your assistance and cooperation in this matter.

Very truly yours,  
Tamkin & Hochberg, LLP

By: \_\_\_\_\_  
Jonathan D. Tamkin

JDT/rr  
cc: Mr. Barry Cadden  
c:\ncp\bdlet.3



# Town of Framingham Massachusetts

98-

## Business Certificate

Fee: \$25.00

Date Issued: May 13, 1998Date Expires: May 13, 2002

In conformity with the provisions of Chapter 110 of the General Laws of Massachusetts, notice is hereby given that the business of:

New England Compounding Center  
Business Name

is conducted at: 697 Waverly St.  
Street Number and Name

Framingham, MA 01702  
Zip

by the following persons:

Name	Resident Address	Signature
1. <u>New England</u>	<u>697 Waverly St.</u>	
2. <u>Compounding Pharmacy</u>		
3. <u>Inc.</u>		
4.		

list additional individuals on back

MIDDLESEX, SS

Date Signed: May 13, 1998Signed and sworn to by Barry J. Cadden

before me

K6

Town Clerk, Designated Clerk, Notary Public, or Justice of the Peace

A True Copy

Attest:

George P. King Jr.  
Town Clerk, Framingham

(seal)

I certify under the penalties of perjury that I, to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes as required under law.

Barry J. Cadden  
Signature of Individual/Corporate Name

Corporate Officer

Social Security or Federal ID # \*Voluntary\* (Your Social Security number will be furnished to the MA Department of Revenue to determine whether you have met all tax obligations.)

This certificate registers the name of your business as required under chapter 110, it offers no authorization regarding the legality of your business, nor does it alter your requirement to comply with local and state zoning ordinances.





Division of Registration Office of Investigations  
100 Cambridge Street, Room 1509  
Boston, Massachusetts 02202  
617-727-7406

SPECIAL ASSIGNMENT FORM

I HEREBY REQUEST THE SERVICES OF AN INVESTIGATOR FROM THE OFFICE OF INVESTIGATIONS.

BOARD: PHARMACY

DETAILS OF PROPOSED UTILIZATION: TO INSPECT APPLICANT NEW ENGLAND COMPOUNDING PHARMACY, 697 WAVERLY STREET, FRAMINGHAM, MA, PURSUANT TO AN APPLICATION FOR A NEW PHARMACY/PHARMACY DEPT. APPLICANT BARRY CADDEN APPEARED BEFORE THE BOARD ON APRIL 14, 1998 TO DISCUSS A STAND ALONE COMPOUNDING SPECIALTY PHARMACY. SCHEDULE AS SOON AS PRACTICABLE BY CONTACTING HELENA TRIPP AT (617) 727-9993.

AUTHORIZED SIGNATURE:

*Charles Downs*

DATE:

4.24.98

FOR OFFICE USE ONLY

ASSIGNMENT NUMBER: BOARD CODE: \_\_\_\_\_ FY \_\_\_\_\_ NO. \_\_\_\_\_

APPROVED BY: \_\_\_\_\_ DATE ASSIGNED: \_\_\_\_\_

INVESTIGATOR ASSIGNED: \_\_\_\_\_ DATE COMPLETED: \_\_\_\_\_

ASSIGNMENT: \_\_\_\_\_

(TO BE COMPLETED BY INVESTIGATOR)

DISPOSITION: \_\_\_\_\_

TIME UTILIZED: \_\_\_\_\_ HRS. INVESTIGATOR INITIALS \_\_\_\_\_

SUPERVISOR SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_

PLEASE COMPLETE ASSIGNMENT INFORMATION ON REVERSE SIDE IF RELEVANT.

**TAMKIN & HOCHBERG, LLP**

**Attorneys at Law**

313 Washington Street, Suite 202

Newton, Massachusetts 02158

Tel (617) 964-2501

Fax (617) 964-7755

Jonathan D. Tamkin, P.C.  
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Karen E. Dumser

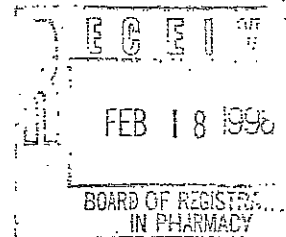
\*Also admitted in Connecticut

Of Counsel  
Alvin C. Tamkin  
Eugene M. Magier, P.C.

February 18, 1998

BY HAND

Charles R. Young, Acting Executive Director  
Board of Registration in Pharmacy  
100 Cambridge Street  
Boston, MA 02202



RE: New England Compounding Pharmacy, Inc.  
Application for New Store

Dear Mr. Young:

Enclosed please find New England Compounding Pharmacy, Inc.'s Application for Registration to Manage and Operate a New Community Pharmacy, including:

- (1) Application for New Store Permit with Articles of Organization and Statement of Corporate Information attached thereto;
- (2) Store Hours Form;
- (3) Massachusetts Controlled Substance Registration Application;
- (4) Certificate of Fitness Application;
- (5) Official Pharmacy Blueprint; and
- (6) Check in the amount of \$310.00 representing all required filing fees.

As we have previously discussed, we have also enclosed New England Compounding Pharmacy's Petition for Waiver of the Provisions of 247 C.M.R. 6.02(4) for Licensure of a Pharmacy pursuant to 247 C.M.R. 14.01.

Kindly time and date stamp the enclosed copy of this letter and return the same to me. Should

Charles R. Young  
Page 2  
February 18, 1998

you have any questions or require any additional information regarding the Application or Petition for Waiver, please contact me.

Sincerely,  
TAMKIN & HOCHBERG, LLP

BY: \_\_\_\_\_

Jonathan D. Tamkin

JDT/  
Enclosures

cc: Carla Conigliaro  
Barry J. Cadden

# The Commonwealth of Massachusetts

William Francis Cahill

Secretary of the Commonwealth

One Ashburton Place, Boston, Massachusetts 02108-1512

## ARTICLES OF ORGANIZATION

(General Laws, Chapter 156B)

### ARTICLE I

The main purpose of the corporation is:

New England Compounding Pharmacy, Inc.

### ARTICLE II

The purpose of the corporation is to engage in the following business activities:

(a) To provide, own, manage, and operate a pharmacy or pharmacies and to provide general and specific pharmacy services;

(b) To do any other acts and things, and to exercise any and all other powers which a corporation organized under the provisions of Massachusetts General Laws Chapter 156B and acts additional, amendatory thereto could do and exercise which now or hereafter may be authorized.

### ARTICLE III

There shall be issued and authorized shares of stock of this corporation as indicated below:

WITHOUT PAR VALUE		WITH PAR VALUE		
TYPE	NUMBER OF SHARES	TYPE	NUMBER OF SHARES	PAYABLE
Preferred	200,000	Common	1,000,000	

### ARTICLE IV

There shall be one class of stock authorized, with a distinguishing designation for each class, prior to the issuance of any shares of stock, the terms of which shall be set forth in the certificate of incorporation and provide a description of the preferences, voting powers, qualifications, and special or relative rights or privileges of each class and of each other class of which shares are outstanding and of each series then constituted within any class.

N/A

### ARTICLE V

The restrictions, if any, imposed by the articles of incorporation upon the transfer of shares of stock of any class are:

N/A

### ARTICLE VI

Under the provisions of law for the conduct and regulation of the business and affairs of the corporation, for ascertaining the location of the business, for the regulation of the powers of the corporation, or of the directors or stockholders or any class of stockholders:

See continuation of Article VI attached hereto.

NEW ENGLAND RECORDING SERVICE, INC.

CONTINUATION SHEET ARTICLE VI

ARTICLE VI - INDEMNIFICATION OF OFFICERS AND DIRECTORS

The Corporation shall, to the extent legally permissible, indemnify any person serving or who has served as a Director or Officer of the Corporation or as its request as a Director, Trustee, Officer, Employee or other Agent of any organization in which the Corporation owns shares or of which it is a creditor, against all liabilities and expenses, including amounts paid in satisfaction of judgments, in compromise or as fines and penalties, and counsel fees, reasonably incurred by him/her in connection with the defense or disposition of any action, suit or other proceedings, whether civil or criminal, in which he/she may be involved or with which he/she may be threatened, while serving or thereafter, by reason of his/her being or having been such a Director, Officer, Trustee, Employee, or Agent, except with respect to any matter as to which he/she shall have been adjudicated to be proceeding not to have acted in good faith in the reasonable belief that his/her action was in the best interest of the Corporation; provided, however, that as to any matter disposed of by a compromise payment by such Director, Officer, Trustee, Employee or Agent pursuant to a consent decree or otherwise, no indemnification either for said payment or for any other expenses shall be provided unless:

(i) such compromise shall be approved as in the best interests of the Corporation, after Notice has been given to the involved such indemnification.

(ii) by a disinterested majority of the Directors then in office; or

(iii) by the holders of a majority of the outstanding shares of the Corporation at the time of the vote, voting as a single class, exclusive of any stock owned by the interested Director or Officer; or

(iv) by the affirmative action by disinterested directors or shareholders, there has been a request or demand by the Director or Officer for indemnification in

**NEW ENGLAND COMPOSING PHARMACY, INC.**

writing of independent legal counsel to the effect that such Director or Officer appears to have acted in good faith in the reasonable belief that his/her action was in the best interests of the Corporation.

Expenses including counsel fees, reasonably incurred by any such Director, Officer, Trustee, Employee or Agent in connection with the defense or disposition of any such action, suit or other proceeding may be paid from time to time by the Corporation in advance of the final disposition thereof upon receipt of any undertakings by such individual to repay the amounts so paid to the Corporation if it is not ultimately determined that indemnification for such expenses is not authorized under this section. The right of indemnification hereby provided shall not be exclusive of or affect any other rights to which any such Director, Officer, Trustee, Employee or Agent may be entitled. Nothing contained in this Article shall affect any rights to indemnification to which Corporation personnel other than such Directors, Officers, Trustees, Employees or Agents may be entitled by contract or otherwise under law. As used in this Article the terms "Director", "Officer", "Trustee", "Employee", and "Agent" include their respective heirs, executors, administrators, and an "Interested Director, Officer, Trustee, Employee or Agent" is one against whom in such capacity the proceedings in question or other proceedings on the same or similar grounds is then pending.

**ARTICLE 33 CONTRACTS WITH INTERESTED PERSONS**

1. Contracts entered into in bad faith, no consent or ratification by this Corporation shall be void, voidable or in any way affected by the fact that it is with an Interested Person.

2. For the purpose of this Article "Interested Person" means person or organization in any way interested in this Corporation as an officer, director, stockholder, employee, or otherwise, or any entity in which any such person or organization or this Corporation is in any way interested.

3. Unless such contract or transaction was entered into in bad faith, no interested person, because of such interest, shall be liable to this Corporation or to any other person or organization.

NEW ENGLAND COMPOUNTING PHARMACY, INC.

for loss or expense incurred on account of such contract or transaction which shall be paid for any gain or profit realized from such contract or transaction.

The provisions of this Article shall be operative notwithstanding the fact that the presence of an Interested Person was necessary to constitute a quorum at a meeting of directors or stockholders of this Corporation at which such contract or transaction was authorized or that the vote of an Interested Person was necessary for the authorization of such contract or transaction.

ARTICLE XI STOCKHOLDERS' MEETINGS

Meetings of stockholders of this Corporation may be held anywhere in the United States.

ARTICLE XII AMENDMENT OF BY-LAWS

The By-Laws may provide that the Board of Directors as well as the stockholders may make, amend, or repeal the By-Laws of this Corporation, except with respect to any provision thereof which by these Articles or by the By-Laws requires action by the stockholders.

ARTICLE XIII ASSETS OR ASSET DISPOSITION

The terms and conditions upon which a sale or exchange of all or substantially all assets, including the good will of the Corporation, or any part thereof, is voted may include the payment therefor in whole or in part in shares, notes, bonds, or other securities of a interest or indebtedness of any voluntary association, trust, joint stock company or Corporation. Such vote may be a subsequent vote which may be given in this regard in the contemplation of proceedings for the dissolution of the Corporation and the proceeds, subject to the right of distribution to the stockholders, to the distribution and payment of any proceeds of the sale or exchange of the assets or any part thereof, whether such proceeds be in cash or in securities or other values to be determined by the Directors.



## NEW ENGLAND CONSTRUCTION, INC.

for loss or expense incurred in relation of such contract or transaction, which shall be available for any gain or profit realized from such contract or transaction.

1. The provisions of this Article shall be operative notwithstanding the fact that the presence of an Interested Person was necessary to constitute a quorum at a meeting of Directors or stockholders of this Corporation at which such contract or transaction was authorized or when the vote of an Interested Person was necessary for the authorization of such contract or transaction.

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workings of stockholders of said corporation may be  
suspended in the United States.

DATE: 10/10/2013 TIME: 10:10:10

1. The Espionage Act provides that the receipt of information is not an offense unless the information is of a nature that it would be of substantial aid to the national defense, and the receipt of such information is prohibited by the Espionage Act. The Espionage Act, except with respect to the receipt of information, is not applicable to the receipt of information by the United States or by the United States Government, and the receipt of information by the United States or by the United States Government is not an offense under the Espionage Act.

Approved: \_\_\_\_\_ Date: \_\_\_\_\_

[illegible]

NEW ENGLAND COMPOUNDING PHARMACY, INC.

ARTICLE SE EIGHTEENTH

This Corporation may become a partner in any general or limited partnership or in any joint venture or in any other business enterprise organized for the purpose of accomplishing any of the purposes contained in this Corporation's Articles of Organization.

ARTICLE SE - RIGHT OF OFFICERS, DIRECTORS AND STOCKHOLDERS TO CONTRACT WITH A CORPORATION

The Corporation may contract and otherwise transact business with any of its Directors, Officers and Stockholders and with corporations, joint stock companies, trusts, firms and associations in which any of them are or may be or become substantially interested as directors, officers, shareholders, members, trustees, beneficiaries or otherwise as freely as though such adverse interest did not impart upon such contract or transaction. No such contract or transaction shall be avoided and no such Director, Officer or stockholder shall be liable to account to the Corporation for any profit realized by him through any such contract or transaction by reason of such adverse interest, not by reason of any fiduciary relationship to such Director, Officer or stockholder to the Corporation arising out of such office or stock ownership; provided the nature of the adverse interest of such officer or Director or stockholder shall have been made known to and disclosed by the Board of Directors to said Board prior to such contract or transaction. Ownership of beneficial interest in an insubstantial amount of the stock or securities of another corporation, joint stock company, trust, firm or association shall not be deemed to constitute an interest adverse to this Corporation and need not be disclosed. The affirming or ratifying vote of a majority of the shares of the common stock of the Corporation outstanding and entitled to vote shall validate any such contract or transaction as against all stockholders of the Corporation, whether or not at the time of such vote, and as against all creditors and owners of bonds, provided that such vote shall be taken at a meeting of the Board of Directors and that specific approval of such contract or transaction shall be provided by a majority of any persons at the time of such vote as may be required by any provision of this paragraph which may be made by the Board of Directors.

ARTICLE VII  
 The effective date of organization of the corporation shall be the date approved and filed by the Secretary of the Commonwealth. If the later effective date is desired, specify such date which shall not be more than thirty days after the date of filing.

ARTICLE VIII  
 The information contained in Article VIII is not a permanent part of the Articles of Organization.  
 The principal office (post office box or the principal office) of the principal office of the corporation, in Massachusetts is  
 657 Waverly Street, Framingham, MA 01701  
 b. The name, residential address and post office address of each officer and director of the corporation is as follows:

NAME	RESIDENTIAL ADDRESS	POST OFFICE ADDRESS
President Carlo Conigliaro	[REDACTED]	Same
Treasurer Carlo Conigliaro	[REDACTED]	Same
Clk. Gregory Conigliaro	[REDACTED]	Same
Director Carlo Conigliaro	[REDACTED]	Same
Gregory Conigliaro	[REDACTED]	Same
Berry J. Canjen	[REDACTED]	Same
Miss M. Conigliaro	[REDACTED]	Same
Director	[REDACTED]	Same

- a. The first year (or years) of the corporation shall end on the last day of the month of December.
- b. The principal office address of the registered agent, being, of the corporation is:

ARTICLE IX  
 By-laws of the corporation have been duly adopted and the provisions were not altered and directors whose names are set forth in the above were duly elected.

IN WITNESS WHEREOF AND UNDER THE HAND AND SEAL OF THE OFFICE, I, the undersigned, have signed and affixed my official seal this 2nd day of December, 1972.

Notary Public for the Commonwealth of Massachusetts, in and for the County of Middlesex, do hereby certify that the foregoing is a true and correct copy of the original filed in my office on this 2nd day of December, 1972.

RECORDS DIVISION OF MASSACHUSETTS

ARTICLES OF ORGANIZATION

(General Laws, Chapter 156C)

I hereby certify that these are the true and correct Articles of Organization  
that have been filed for record in the office of the Secretary of the  
Commonwealth of Massachusetts and that the same have been compared  
with the original and found to be correct and true and that the same  
have been filed for record in the office of the Secretary of the  
Commonwealth of Massachusetts on the 7th day of February 1998

A TRUE COPY ATTEST

*William Francis Galvin*

WILLIAM FRANCIS GALVIN  
SECRETARY OF THE COMMONWEALTH

DATE 2/25/98  
CLERK SSW

*William Francis Galvin*

WILLIAM FRANCIS GALVIN  
Secretary of the Commonwealth

NOTE: One of our records of the total authorized capital  
stock, but not less than \$100,000, of the shares of  
stock with a par value of \$1.00, and the stock should be filed  
to have a par value of \$1.00 per share.

TO BE FILED WITH ORGANIZATION

Photocopy of document to be sent to:

\_\_\_\_\_  
MARIA A. FORTIN, Esq.

\_\_\_\_\_  
113 Washington St., Suite 203  
Newton, MA 02158

\_\_\_\_\_  
Tel: 617-552-1111